

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

PROCTER & GAMBLE COMPANY,

Plaintiff,

v.

MCNEIL-PPC, INC.,

Defendant.

OPINION and ORDER

08-cv-251-bbc

Plaintiff Procter & Gamble Company owns United States Patents Nos. 6,949,240 (the '240 patent) and 6,551,579 (the '579 patent), both of which are directed towards tooth whitening products. Plaintiff brought this action for patent infringement against defendant McNeil-PPC, Inc., alleging that defendant's Listerine Whitening® Quick Dissolving Strips infringe both patents. In response, defendant filed a counterclaim in which it seeks a declaration that the claims of both the '240 and '579 patents are invalid and that the claims of the '240 patent are unenforceable as a result of inequitable conduct and fraud.

Now before the court are the parties' motions for construction of disputed claim terms in the '240 and '579 patents. On September 19, 2008, the parties filed their cross motions requesting construction and a hearing of disputed terms in the '240 and '579

patents. Plt.'s M., dkt. #61, Dft.'s M., dkt. #65. In an order issued October 3, 2008, I denied the parties' request for a hearing to construe the disputed terms. Order, dkt. #80. However, upon reviewing the briefs in support of claims construction and the patent claims, I agree that construction of the disputed terms is appropriate. I find that the jury would benefit from having a judicial construction of the following disputed terms from plaintiff's patents:

- “a layer of tooth whitening composition” (‘240 Pat., claims 1 and 14) and “a layer of tooth whitening substance” (‘579 Pat., claims 1 and 11);
- “strip of material” (‘240 Pat., claims 1 and 14)(‘579 Pat., claims 1 and 11)
- “a gelling agent” (‘240 Pat., claims 9 and 19) (‘579 Pat., claims 1, 3-6, 11 and 13-15);
- “disposed on said strip of material” (‘240 Pat., claims 1 and 14);
- “release liner” (‘579 Pat., claims 1 and 11);
- “less affinity for said tooth whitening substance than said tooth whitening substance exhibits for itself and for said strip of material” (‘579 Pat., claims 1 and 11);
- “thin” (‘579 Pat., claim 11).

Also before the court is defendant's motion for leave to file an amended answer and counterclaim to add new facts in support of its affirmative defense and counterclaim of

inequitable conduct with respect to the '240 patent and add a new affirmative defense and claim of inequitable conduct with respect to the '579 patent. Plaintiff opposed only the request for leave to add the new affirmative defense and counterclaim of inequitable conduct for the '579 patent. Defendant's motion to file an amended answer and counterclaim will be granted with respect to its affirmative defense and counterclaim for the '240 patent and will be denied with respect to its new counterclaim for inequitable conduct for the '579 patent.

OPINION

I. CLAIMS CONSTRUCTION

A. Standard for Construing Claim Terms

When construing disputed terms in a claim, a court should generally give the terms their ordinary and customary meaning. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). The ordinary and customary meaning of terms "is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." Phillips v. AWH Corporation, 415 F. 3d 1303, 1313 (Fed. Cir. 2005). The Court of Appeals for the Federal Circuit has held that the person of ordinary skill in the art would read a term both in the context of the claim in which it appears and "in the context of the entire patent, including the specification." Id. (citing Multiform Desiccants, Inc. v.

Medzam, Ltd., 133 F.3d 1473, 1477 (Fed. Cir. 1998)). Additionally, a patent's prosecution history can be relevant to construing disputed terms of a patent because it "provides evidence of how the PTO and the inventor understood the patent." Phillips, 415 F.3d at 1317.

Extrinsic evidence such as the opinion of experts in the field can be useful in illustrating how a term is commonly understood in the field. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1308-09 (Fed. Cir. 1999). However, extrinsic evidence should be given less weight than the intrinsic evidence and viewed within the context of that intrinsic evidence. Phillips, 415 F.3d at 1318-19; see also Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 595 (1993) (expert evidence can be misleading and difficult to evaluate).

B. Asserted Claims

The '240 patent discloses a tooth whitening product that contains a chemical agent disposed on a strip of material. The '579 patent discloses a delivery system for a tooth whitener that includes a chemical agent on a strip of material and a release liner. The asserted novelty of the patents is that they reveal a method for delivering a high concentration of hydrogen peroxide, a chemical agent used for whitening, in a manner that does not irritate the tissue inside a person's mouth. The patents are directed toward

products for at-home consumer use as opposed to supervised dental visits.

The disputed terms in the '240 patent appear in independent claims 1 and 14 and dependent claims 2-7, 9, 12-13 and 17-19. Independent claim 1 discloses:

1. A tooth whitening product, comprising:

a **strip of material** sized to cover the front surface of one or more teeth and soft tissue adjacent the front surface of the one or more teeth;

a **layer of a tooth whitening composition disposed on said strip of material**, wherein said whitening composition comprises a peroxide active having a concentration greater than about 7.5% by weight of said tooth whitening composition; and

wherein said tooth whitening composition has a peroxide density less than about 1.3 mg/cm².

'240 Pat., col. 17, lns. 19-30. Independent claim 14 mirrors most of the language of claim

1.

The disputed terms of the '579 patent appear in independent claims 1 and 11 and dependent claims 3, 13, 16-18 and 20-23. Independent claim 1 discloses:

1. A delivery system for whitening teeth, comprising:

a **strip of material** sized to cover a front surface of a plurality of teeth;

a **layer of a tooth whitening substance** in contact with said strip of material, said tooth whitening substance comprising a **gelling agent** and a whitening active selected from the group consisting of peroxides, metal chlorites, perborates, percarbonates, peroxyacids, hypochlorites, and combinations thereof; and

a **release liner** having a coating thereon, wherein said release liner exhibits **less affinity for said tooth whitening substance than said tooth whitening substance exhibits for itself and for said strip of material.**

579 Pat. col. 14, lns. 34-44. Independent claim 11 mirrors most of the language of claim 1; unlike claim 1 it contains the disputed term “thin.” Claim 11 reveals, in relevant part: “A delivery system for whitening teeth, comprising: a flexible strip of material . . . ; a **thin** layer of tooth whitening substance in contact with said flexible strip of material....” 579 Pat., col 15, lns. 3-7.

C. Disputed Terms in Both Patents

_____Because both patents are closely related, they share similar claim terms, three of which are disputed. The patents use the terms in a similar fashion and contain no limiting language that indicate that these common terms are to be defined differently. Moreover, plaintiff, who owns the patents, does not argue that terms should be construed differently from one patent to the other. Therefore, because these patents have a common owner and use the disputed terms in an similar manner, I will follow the parties’ lead and assume that the claim terms should have the same meaning in both patents.

1. “layer of tooth whitening composition” as used in claims 1 and 11 of the ‘240 patent and “layer of tooth whitening substance” as used in claims 1 and 11 of ‘579 patent

Plaintiff's construction: No construction necessary or, a layer that contains a tooth whitening active.

Defendant's construction: A layer that contains a tooth whitening active and that is different from the strip of material.

The parties dispute whether the “layer of tooth whitening composition” or “substance” is a separate component distinct from the “strip of material.” Defendant argues resolution of this dispute requires the court to consider the entirety of the claim language that describes the “layer” as “disposed on,” ‘240 Pat, col. 17, lns. 23-24, or “in contact with” the “strip of material.” ‘579 Pat., col. 14, lns. 36-37. I agree that the disputed terms must be read in the context of the claim language and that the claim describes a “layer” and a “strip of material” as two separate objects.

Claim construction always begins with the claim language. In this case, the claims indicate that in relation to the strip of material, the layer is either “disposed on” or “in contact with” the strip of material. According to the dictionary, to “dispose” means “to put in place; set in readiness.” Merriam-Webster’s Collegiate Dictionary 335 (10th ed. 1997). In addition, “contact” is defined as a “union or junction of surfaces.” *Id.* at 249. Defendant points out that the plain meaning of these terms requires a relationship between two separate objects. Plaintiff offers no contrary definitions or examples from the specification to suggest that these words are being used differently from their dictionary meaning in either

the '240 or the '579 patent. Pfizer, Inc. v. Teva Pharmaceuticals, USA, Inc., 415 F. 3d at 1322-23 (“judges may ‘rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents’”)

The specifications of the patents bolster defendant’s reading. The elements and features of the layer of whitening composition or substance, which is also referred to as the oral care substance, and the strip of material are defined separately and refer to different objects. Specifically, the '579 patent describes the strip of material as serving as a barrier for an oral care substance, '579 Pat., col. 3, lns. 35-36, as well as a base on which the oral care substance is coated. '579 Pat., col. 4, lns. 9-12. In the '240 patent, the “layer” is described as being “on or in contact with the strip of material and release liner.” '240 Pat., col. 7, lns 34-36. Both patents refer repeatedly to the “layer” and “strip” as separate objects.

Although the parties have offered proposed constructions, I will not adopt either construction because neither helps to clarify the meaning of the term. However, I conclude that the “layer of tooth whitening composition” disclosed in claims 1 and 14 of the '240 patent and the “layer of tooth whitening substance” disclosed in claims 1 and 11 of the '579 patent are separate from the “strip of material” disclosed in those claims.

2. “strip of material” in claims 1 and 14 of the '240 patent and claims 1, 10 and 11 of

the '579 patent

Plaintiff's construction: No construction necessary

Defendant's construction: A "strip of material" does not include an object that disintegrates or dissolves in the mouth during use. A "strip of material" is a piece of material that has structural integrity separate and apart from the layer of a tooth whitening substance of composition recited in the claims, and that has the following mandatory characteristics: it is conformable to the contoured surfaces of the teeth (and, in the case of the '579 patent, is conformable without permanent deformation); it serves as a substantially water impermeable barrier during use; it has low flexural stiffness; and it is easily removable and intact after use. In addition, the term 'strip of material' is indefinite as to the shapes that fall inside or outside the scope of the claim term.

Defendant dispute the meaning of "strip of material" on two alternate theories. First, defendant argues that a "strip of material" is insolubly ambiguous because the patents do not indicate what shapes fall within and outside the scope of the term. Second, defendant contends that a strip of material cannot "dissolve" and that it must include five mandatory limitations found in the specification. I agree with plaintiff that these two positions taken by defendant appear to be in tension with each other; regardless, I conclude that the patents disclose a range of possible shapes for a "strip of material" and therefore, the term is not

insolubly ambiguous. Further, I find that neither the claim language nor the specification requires that the claim be construed to include defendant's asserted limitations except the "flexural stiffness" limitation in both patents and the "substantially water impermeable limitation" in the '579 patent.

a. Indefiniteness: shape of "strip of material"

The standard for indefiniteness is high. "If the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree," the claim is sufficiently clear to avoid indefiniteness. Exxon Research and Engineering Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001). A claim is indefinite only if the "claim is insolubly ambiguous, and no narrowing construction can properly be adopted." Id.

In the '240 patent, the inventors described a strip of material as "sized to cover the front surface of one or more teeth and soft tissue adjacent said front surface of the one or more teeth." '240 Pat., col. 17, lns. 20-23. In the '579 patent, they described a strip of material as "sized to cover a front surface of a plurality of teeth." '579 Pat., col. 14, lns. 34-36. Both patents disclose the shape of strip of material as one that could cover either one or more teeth. From this description, one knows what the general metes and bounds are and what shapes would not work, such as circles, cubes, pyramids or disks. Thus, contrary to

defendant's contention, it is possible to narrow the possible universe of shapes that could be a "strip of material" claimed in both the '240 and '579 patent. It follows that a "strip of material" is not indefinite.

b. Limitations

Although plaintiff is correct that courts should be cautious about reading limitations from preferred embodiments into the claim language, a court cannot disregard the specification altogether. It is an essential tool in discerning the meaning of claim terms when there is a lack of accepted meaning in the art. Irdeto Access, Inc. v. Echostar Satellite Corp., 383 F. 3d 1295, 1300 (Fed. Cir. 2004) (when no accepted meaning, "[t]he duty . . . falls on the patent applicant to provide a precise definition for the disputed term."). In this case, the parties dispute what qualities a "strip of material" must have in order to practice either the '240 or '579 patent. Most of the limitations that defendant proposes are merely qualities found in preferred embodiments or unfounded extrapolations defendant draws from the specification. The only limitations implicitly required are that the "strip of material" in the '240 and '579 patents have a "low flexural stiffness" and that the "strip of material" in the '579 patent be "substantially water impermeable."

1) limitations found in the specification: "flexural stiffness" and "substantially water

impermeable”

It is clear in both the ‘240 and ‘579 patent when the inventors are discussing “preferred embodiments” in the specification. In certain instances, however, the specification describes the claim terms generally.

a) limitations in the ‘240 patent

The specification states that “the strip of materials 12 *should* have a relatively low flexural stiffness so as to enable it to drape over the countered surfaces of the teeth with very little force being exerted. . .” ‘240 Pat., col. 11, lns. 10-13 (emphasis added). In this instance, the patent is referring to the “strip of material” generally and not merely to a preferred embodiment of the invention, as it clearly does in other instances. E.g., ‘240 Pat., col. 3, lns. 13-18 (detailed description of preferred embodiments); col. 5, lns. 17-18 (“Referring again to FIG. 9 and while not intending to be bound by any theory”); col. 6, lns. 19, 41, 66 (indicating descriptions of particular embodiments). Therefore, I agree with defendant that this quality of the strip of material is not an optional but a mandatory quality. However, I do not agree with defendant that the strip of material must always be “water impermeable.” Defendant identifies no language in the specification that explicitly describes the “strip of material” as being “water impermeable.” Accordingly, I will not import this limitation into the term “strip of material” as used in the ‘240 patent.

b) limitations in the '579 patent

The specification of the '579 patent provides that "[i]n the present invention, the strip of material has a flexural stiffness of less than about 5 grams/cm . . ." '579 Pat., col 4, 34-35. The patent also describes the importance of the "strip of material" having a "low flexural stiffness." '579 Pat., col 4, ln. 22 - col. 5, ln. 20. "When a patent thus describes the features of the "present invention" as a whole, this description limits the scope of the invention." Verizon Services Corp. v. Vonage Holdings Corp., 503 F. 3d 1295, 1308 (Fed Cir. 2007). Therefore, I agree with defendant that as in the '240 patent, this is not an optional but a mandatory feature of the '579 patent.

The specification also discloses possible materials that might compose the "strip of material" and whether it may contain multiple layers of the material. However, the specification states that "regardless of the number of layers, the strip of material is substantially water impermeable." '579 Pat., col 3, 51-52. This section also refers to the "strip of material" generally and not as a preferred embodiment. The use of the word "regardless" in this instance suggests that no matter what substance constitutes the "strip of material," it must be "substantially water impermeable." Therefore, I conclude that this feature is a mandatory feature of the '579 patent.

2) limitations not found in specification

Although the parties dispute a number of issues related to the term “strip of material,” their core dispute focuses on whether plaintiff’s patents disclose a strip of material that can dissolve in the user’s mouth. Defendant asserts that the main difference between its whitening product and plaintiff’s is that the Listerine Whitening® Quick Dissolving Strips dissolve in the user’s mouth. Defendant believes that plaintiff’s patent discloses a product that does not dissolve because the patents nowhere mention that the “strip of material” dissolves. In addition, as defendant points out in support of its non-dissolution argument, the ‘579 patent requires that (1) the strip of material must be removed intact from the mouth; (2) it must be conformable to the contoured surfaces of the teeth without permanent deformation; and (3) it must have structural integrity. Defendant is partially correct. It is correct in saying that the patents do not mention whether the strip of material dissolves but it does not acknowledge that the patents do not require that the strip be non-dissolving or require expressly or implicitly that the strip of material must retain any of the other limitations defendant would assign it.

With respect to the argument regarding dissolution, defendant suggests that because the strip of material “serves as a protective barrier . . . to prevent saliva from contacting the tooth whitening composition [or substance],” ‘240 Pat., col. 3, lns. 27-31; ‘579 Pat., col. 3, lns. 35-37, the strip cannot dissolve in the mouth. Defendant assumes that because the strip must be a protective barrier it cannot later dissolve, but it points to no language in the

specification and offers no evidence or expert testimony to support its assumption that a protective barrier cannot dissolve at some point. I conclude that the requirement that the “strip” function as a “protective barrier” includes no requirement that a strip of material not dissolve.

In arguing that the “strip of material” must be removable and therefore non-dissolvable, defendant identifies a number of passages in the specification that it believes indicate that the strip of material must be removed from the mouth. One of the passages states that “the strip of material [can be] easily removed by the wearer by simply peeling off the strip of material using ones [sic] finger, fingernail or rubbing with a soft implement such as a [sic] cotton balls and swabs or gauze pads.” ‘579 Pat., col. 4, ln. 64 - col. 5., ln. 2. A second passage states that “The delivery system is easily removable from the oral surfaces without the use of an instrument, a chemical solvent or agent or excessive friction.” ‘579 Pat., col. 5, lns. 2-4. Contrary to defendant’s proposed construction requiring non-dissolution, the specification says nothing about the strip’s being removed from the mouth or that it be removed intact; it requires only that the strip of material be removable from the oral surface, which is the user’s teeth. Therefore, this proposed limitation will not be read into the ‘579 patent.

Defendant cites the requirement in the specification of the ‘579 patent that the strip of material be “easily conformable to tooth surfaces without permanent deformation.” This

citation does not advance defendant's argument because the easily conformable feature is not a "mandatory" feature found in "Strip of Material" section of the '579 patent. Rather it is found only in the section describing "preferred embodiments" of the '579 patent. A court should not import a limitation from the preferred embodiment unless there is evidence in the intrinsic record that the limitation was meant to apply generally. Phillips, 415 F.3d at 1323 ("although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments"); Nazomi Communications, Inc. v. ARM Holdings, PLC, 403 F.3d 1364, 1369 (Fed. Cir. 2005). Defendant has offered no evidence that the inventors intended the limitation to apply generally. Therefore imposing the limitation would be improper.

Defendant's final argument supporting non-dissolution is that the strip of material must have "structural integrity" because the strip of material must be separate from the layer of tooth whitening substance and must be removable after use. However, defendant cites no section of either patent in which the inventors describe the strip of material as having "structural integrity." Because it would be error to impose any of the above limitations that are not clearly disclosed, I will not adopt the following limitations on the "strip of material" proposed by defendant: "does not disintegrate or dissolve in the mouth during use," "easily removable intact after use," "easily conformable to tooth surfaces without permanent deformation," and "has structural integrity"

In light of the preceding analysis on the term “strip of material,” I will not adopt either parties’ proposed construction of the term. However, I do conclude that a “strip of material” as disclosed in both the ‘240 and ‘579 patents has low flexural stiffness and that a “strip of material” as disclosed in the ‘579 patent is substantially water impermeable.

Court’s construction: The “strip of material” disclosed in claims 1 and 14 of the ‘240 patent has a low flexural stiffness but does not have to be substantially water impermeable. The “strip of material” disclosed in claims 1 and 11 of the ‘579 patent has a low flexural stiffness and is substantially water impermeable. The “strip of material” disclosed in both patents is not indefinite and does not contain the following limitations: (1) it cannot dissolve or disintegrate in the mouth; (2) it is conformable to the countered surfaces of the teeth; (3) it is easily removable and intact after use and (4) it has structural integrity.

3. “gelling agent” as used in claims 9 and 19 of the ‘240 patent and claims 1, 3-6, 11 and 13-15 of the ‘579 patent

Plaintiff’s construction: No construction necessary

Defendant’s construction: An ingredient in the tooth whitening substance that causes the tooth whitening substance to form a gel

The parties agree that a “gelling agent” is an agent that has the ability to cause

another substance to become a gel. However, defendant argues that a gelling agent as used in the '240 and '579 patent *must cause* a gel to be formed. Once again, defendant contends that the plain meaning of the term requires its proposed construction. Although I agree that the plain meaning of the term should be applied, I conclude that the plain meaning does not require that the gelling agent cause a gel to be formed in every instance.

The claim language of the '240 patent and the '579 patent offers no guidance on this issue. In both patents, a gelling agent is described as part of either a tooth whitening composition or a tooth whitening substance. Pat. '240, col. 18, lns. 1-3; Pat. '579, col. 14, lns. 38-40. Neither patent says that the tooth whitening composition or substance is formed into a gel.

In support of its construction, defendant cites the specification of the '579 patent and plaintiff's "internal documents" for the proposition that an agent is a gelling agent only when it forms a gel. According to defendant, the specification explains that a "gel" is formed by "gelling agents": "The gel is a high viscosity matrix formed from gelling agents known in the art." '579 Pat., col. 11, lns. 1-3. However, this does not prove that gelling agents must always cause a gel to be formed or that a tooth whitening composition or substance always forms a gel. Moreover, the specification of the '579 patent explains that the use of a gel is only a preferred embodiment, stating that "the oral care substance of the present invention can be in a variety [of] forms, but, *most preferable* is a gel, particularly an aqueous gel." '579

Pat., col. 10, ln. 66 - col. 11, ln. 1 (emphasis added). In other words, the oral care substance is not always formed into “gel.” Defendant cites nothing in the specification that indicates that when a gel is not formed a gelling agent is not present.

Contrary to defendant’s suggestion, common sense does not dictate that the presence of a gelling agent shows that a gel must be formed. As plaintiff argues, there will be instances in which certain compounds cause a substance to change or alter only when a certain amount of that object is present. For example, one drop of colored dye might not visibly change the color of water but a number of drops will. Does that mean that the single drop of dye is not a dyeing agent? Perhaps a “gelling agent” is different from a dyeing agent. If it is, defendant has offered no evidence to show that it is. Therefore, I will not adopt defendant’s proposed construction.

Court’s construction: an agent that has the ability to form a gel

D. Disputed Terms in ‘240 Patent

1. “disposed on said strip of material” as used in claims 1 and 14

Plaintiff’s construction: No construction necessary

Defendant’s construction: Placed on and supported by said strip of material

As an initial matter, defendant argues that plaintiff admitted that the plain and

ordinary meaning of “disposed on” is “placed on.” Kiel Aff., dkt. #67-19, Exh. R, at 60, lns. 5-10. However, it is unclear how this definition clarifies the meaning of the term. Defendant cites no language in the claim or the specification that suggests that “placed on” is necessary to explain the term, which is readily understandable. The phrases “disposed on” and “placed on” are essentially synonymous. Thus, there appears to be no dispute over the meaning of the term. Therefore, defendant’s proposed phrase will not be substituted for the language chosen by the patent holder.

The parties’ real dispute is whether the “strip of material” disclosed in claims 1 and 14 must support the tooth whitening composition that is “disposed on” the strip. Plaintiff argues that neither the claim language nor the specification support this additional limitation. I agree.

According to defendant, the patent holder’s decision to use the language “disposed on said strip of material” in the ‘240 patent instead of “in contact with said strip of material” as used in the ‘579 patent shows that the former was not meant to designate location. Rather, defendant argues, the phrase “disposed on” indicates that in the ‘240 patent the strip of material supports the “tooth whitening composition.” For further support, defendant cites a passage in the specification that describes a preferred embodiment that reads: “the strip of material 12 is used to apply the tooth whitening composition to the teeth.” ‘240 Pat., col. 3., lns. 25-27. By itself, a preferred embodiment does not require that all other

embodiments of the patent have the same qualities. Defendant cites no additional examples to support its construction. Moreover, this passage says nothing about the strip of material “supporting” the tooth whitening composition, except in the broadest sense. In the absence of any language in the claim or the specification that indicates that “disposed of” requires the strip of material to support the tooth whitening composition that construction will not be adopted.

Court’s construction: No construction necessary

E. Disputed Terms in ‘579 Patent

1. “release liner” as used in claim 1 and 11

Plaintiff’s construction: No construction necessary or, alternatively, a liner from which the tooth whitening product can be removed.

Defendant’s construction: A liner that is removably attached to the tooth whitening substance. The release liner is not the package or any of its parts.

The parties dispute whether a release liner is attached to the tooth whitening substance and whether a package could be considered a “release liner.” The language of claims 1 and 11 offers little guidance. The claims disclose that a “release liner” contains a “coating” and has “less affinity for the tooth whitening substance that is on the strip of

material.” ‘579 Pat., col 14, lns. 42-44, col. 15, lns. 15-18. Neither of these disclosures indicates whether the release liner is meant to be “attached” to the oral care substance or whether it could not be a package.

Defendant contends that the specification clearly indicates that the “release liner” was meant to be attached to a tooth whitening substance disposed on the strip of material and that the prosecution history of the ‘579 patent and plaintiff’s “internal evidence” show that the patent was not intended to cover “packages.”

With respect to whether the “release liner” is attached to the tooth whitening substance, defendant cites two passages in support of its position. The first passage states:

FIG. 10 is a cross-sectional view of an alternative embodiment of the present invention, taken along section line 10-10 of FIG. 9, showing release liner attached to the strip of material by the oral care substance on the strip of material.

‘579 Pat., col. 2, lns. 31-34. This passage does not indicate how a release liner is removed, but it says that the “release liner” is attached to the strip of material with the tooth whitening substance in one embodiment of the invention. The second passage offers more support for defendant’s position:

FIGS. 9 and 10 shows [sic] optional release liner 27. Release liner 27 is attached to strip of material 12 by oral care substance 14. Oral care substance 14 is on the side of strip of material 12 facing release liner 27. This side is applied to the tooth and gum surfaces once *release liner 27 is removed*.

‘579 Pat., col. 3, lns. 29-33 (emphasis added). This passage shows that in one instance the

release liner is both attached and removed from the strip of material with the tooth whitening substance. However, this is only one embodiment of the patent.

An embodiment may serve to limit a claim only if it is clear that the patentee intends the claims and embodiments to be strictly coextensive, Phillips, 415 F.3d at 1323, or the examples used make it clear that a limitation was intended. On Demand Machine Corp. v. Ingram Industries, Inc., 442 F.3d 1331, 1339-40 (Fed. Cir. 2006) (limitation warranted because specification used term “customer” repeatedly in specialized context); Nystrom v. TREX Co., Inc., 424 F.3d 1136, 1144-45 (Fed. Cir. 2005) (limitation warranted because written description and prosecution history consistently used term “board” to refer to wood decking materials cut from a log). Defendant cites no other examples in the specification that show that a release liner is attached to the tooth whitening substance. Because the patent makes no other references to a method for attaching a release liner, there is no reason to believe that this one example was intended to disclose a claim limitation.

Next I consider defendant’s argument regarding the prosecution history of the ‘579 patent. According to defendant, the prosecution history clearly shows that a “release liner” is not a package because the patent examiner rejected the patent application immediately preceding the ‘579 patent which did not claim a “release liner,” Dft.’s Br., dkt. #66, at 32-33, and rejected it on the ground that “four prior art references disclose[ed] delivery systems with layers of tooth whitening substance provided in individual packages.” Dft.’s Br., dkt.

#66, at 32. Plaintiff's ensuing application, which was approved, contained the "release liner" claim. Therefore, defendant concludes, the patent examiner did not consider a "release liner" to include packages.

During the prosecution of a patent, the patentee may disclaim certain embodiments of its invention, but such a disclaimer must be "clear and unmistakable" to have legal effect. Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc., 438 F.3d 1123, 1136 (Fed. Cir. 2006). The patent examiner did not say explicitly that it did not consider "release liner" to include packages. Defendant does not cite any evidence that it was because of a lack of "release liner" that the prior application was rejected. Nothing in defendant's summary of the prosecution history forecloses the possibility that a release liner is either a type of package or a feature of a package.

Defendant also argues that plaintiff made an implicit disclaimer of a "release liner" that was a "package." During the application process for the '579 patent, the patent examiner asked plaintiff to identify co-pending applications "with a claim to a release liner." Plaintiff failed to disclose pending applications reciting a "package." Dft.'s Reply Br., dkt. #92, at 23 ("[Plaintiff] did not, however, identify in response to the Examiner's request three other co-pending applications that included claims reciting a 'package'—the same package that [plaintiff] now asserts is a release liner").

The problem with defendant's argument is that it assumes too much. It is possible

that certain packages could be release liners but not all packages. Defendant has given the court no basis for believing that the patents not disclosed contained the features necessary to disclose a release liner.

Defendant relies on internal evidence from plaintiff, that is, a summary of a meeting of plaintiff's scientists and an internal office memorandum. In both documents, the plaintiff's scientists are discussing the possibility of eliminating the "release liner" from the product. Although a court may consult extrinsic evidence to shed light on the relevant art, the Court of Appeals for the Federal Circuit has cautioned that this type of evidence is "less significant" and not as reliable as intrinsic evidence in determining "the legally operative meaning of claim language." Phillips, 415 F. 3d at 1317-18. The evidence offered by defendant is a prime example of the unreliability of extrinsic evidence. The documents cited by defendant make no reference to the '579 patent. It is unclear whether any of the information revealed in these memos had anything to do with the '579 patent or whether any of the individuals involved in writing these memos were involved in either the drafting of the '579 patent or in the invention claimed by the patent. These documents offer no definitive guidance on how to interpret the term "release liner."

I am not persuaded that either party's proposed construction is correct. However, I am persuaded that neither the specification nor the prosecution history of the '579 patent establishes that a "release liner" cannot be a package.

2. “less affinity for said tooth whitening substance than said tooth whitening substance exhibits for itself and for said strip of material” as used in claims 1 and 11

Plaintiff’s construction: No construction necessary

Defendant’s construction: some affinity for said tooth whitening substance, which affinity is less than the affinity that said tooth whitening substance exhibits for itself and for said strip of material.

The parties dispute whether a release liner that has “less affinity” for the “tooth whitening substance” must have at least “some affinity” for the “tooth whitening substance.” Plaintiff takes the reasonable position that the ordinary meaning of the term would include zero affinity. “Zero” is less than any positive affinity.

Relying on two references in the specification in which the “release liner” is described as being “attached” to the strip of material by the oral care substance, defendant argues that an object “attached” to another object must have at least some affinity for the other object. I am not persuaded from my own reading of the specification that the inventors clearly intended to limit the phrase “less affinity for” to mean only “some affinity.” The two passages on which defendant relies cite the same figure, which is only a preferred embodiment. The fact that a “release liner” is “attached” in one embodiment does not mean that it must be attached in every case.

Defendant has pointed to no language in the claim or the specification to establish

that the patent requires “some” affinity between the “release liner” and the tooth whitening substance. Therefore, I will not adopt its proposed construction. I conclude that “less affinity for” could include zero affinity.

3. “thin” as used in claim 11

Plaintiff’s construction: No construction necessary or, having a thickness that is less than the width and length

Defendant’s construction: Indefinite

Defendant argues that the term “thin” in “a thin layer of tooth whitening substance” is not defined in the claim language or in the specification and is insolubly ambiguous. As I noted in discussing the term “strip of material,” a party that argues that a term is indefinite bears a heavy burden. It must show that “no narrowing construction can properly be adopted.” Exxon Research and Engineering Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001). Although defendant is correct that the term “thin” is not defined explicitly in the patent, the term is not hopelessly ambiguous. At the same time, I agree with defendant that plaintiff’s proposed construction has no basis in either the claim language or the specification and I will not adopt it.

The ‘579 patent is intended to create a product that contains “a non-bulky active containment . . . that will permit the wearer to use the system during social discourse

without interfering with the wearer's speech or appearance." '579 Pat., col 1, lns. 26-28. Therefore, the patent reveals that a "thin" layer of "tooth whitening substance" is a layer that does not impede speech or affect appearance. Otherwise, the purpose of the invention would be frustrated. Although this does not offer a precise measurement, it suggests a range of measurements. It is not so broad and infinite that the term is indefinite.

II. DEFENDANT'S FIRST AMENDED ANSWER AND COUNTERCLAIM

Rule 15(a) of the Federal Rules of Civil Procedure provides that "a party may amend [its] pleading once as a matter of course at any time before a responsive pleading is served"; otherwise, amendment is permissible "only by leave of court." Whether to grant leave to amend a pleading pursuant to Rule 15(a) is within the discretion of the trial court, Sanders v. Venture Stores, Inc., 56 F.3d 771, 773 (7th Cir. 1995), and leave "shall be freely given when justice so requires." Fed. R. Civ. P. 15(a). Although leave to file an amended or supplemental complaint should be granted liberally, a request to amend may be denied on several grounds, including undue delay, undue prejudice to the party opposing the motion, or futility of the amendment. Sound of Music v. Minnesota Mining and Manufacturing Co., 477 F.3d 910, 922-23 (7th Cir. 2007); Butts v. Aurora Health Care, Inc., 387 F.3d 921, 925 (7th Cir. 2004).

From plaintiff's brief in opposition, I understand that plaintiff does not challenge

defendant's proposed addition of facts regarding its claims of inequitable conduct during prosecution of the '240 patent. In addition, because this affirmative defense and counterclaim were included in defendant's original answer and counterclaim filed on June 16, 2008, dkt. #22, plaintiff will not be prejudiced by the amendment. Defendant's motion to amend its answer and counterclaim to allege new facts regarding prosecution of the '240 patent will be granted.

However, defendant seeks also to add a new affirmative defense and counterclaim for inequitable conduct during prosecution of the '579 patent. It has not shown that its "recent" discovery of the facts relating to its new affirmative defense and counterclaim outweigh its four-month delay in filing this additional claim and the resulting prejudice plaintiff would incur if the amendment were allowed.

Defendant argues that the facts underlying the '579 inequitable conduct claim were not known to it until plaintiff filed its motion requesting claims construction on September 19, 2008 and its response brief on October 14, 2008. Specifically, defendant argues that it did not bring its inequitable conduct claim until it learned that the *inventors* of the '579 patent believed the term "release liner" could include packages and purposefully withheld certain co-pending patent applications that would demonstrate this point. Dft.'s Br. in Supp. of M. Amend, dkt. #111, at 16 ("In its opening claim construction brief, filed on September 19, 2008, [plaintiff] divulged for the first time that, contrary to the '579 patent

applicants' representation during prosecution, the inventors actually believed or 'envisioned' during prosecution that the term 'release line' covers packaging, such as that in the accused Listerine Whitening Strip.").

However, most of the facts relating to defendant's inequitable conduct claim are based on the prosecution history of the '579 patent regarding the claim term "release liner." The prosecution history is a public document that was available to defendant well before plaintiff filed its motion for claims construction. In fact, defendant's brief requesting claims construction contains many of the same facts from the prosecution history that it wants to add now. Moreover, defendant's claims construction brief filed on September 19, 2008 also asserts that plaintiff "believed" that the term release liner does not include a package. Dft.'s Br., dkt. #66, at 31 ("according to [plaintiff's] own scientists, a coated package would not be an example of a release liner; it would eliminate the release liner"); *id.* at 32 ("again according to [plaintiff's] own scientists, the package would not be a release liner"); *id.* at 33 ("When [plaintiff] presented new claims with the release liner claim term, [plaintiff] never told the Patent Office that a 'release liner' could be a package.").

The single fact that the inventors intended a "release liner" to cover a package adds little to what defendant already knew regarding plaintiff's "state of mind" during the prosecution history and definitely does not warrant the ensuing delay. Defendant could have filed its amendment after plaintiff filed its first brief regarding claims construction but

it waited six weeks before raising this issue to plaintiff, Dft.'s M. to Amend., dkt. #111, at 8, and one more month before filing its amended counterclaim. Therefore, defendant cannot argue that there was "good cause" for its delay in filing its '579 claim. Extreme Networks, Inc. v. Enterasys Networks, Inc., 07-cv-229-bbc, 2007 WL 5448209, at*1 (W.D. Wis. Dec. 31, 2007) (denying request for leave to amend complaint to add new inequitable conduct claims where claims derived from prosecution history and plaintiff did not explain how new "facts" learned in discovery justified delay in amending pleadings).

Second, defendant argues that plaintiff will not be prejudiced by the amendment because the original answer and counterclaim contained an inequitable conduct claim and discovery in this case is ongoing and not set to close until May 1, 2009. Although defendant's original counterclaim contained inequitable conduct claims, these claims were directed at the '240 patent. Defendant's submissions of the claims relating to the '579 patent came two days before initial expert reports were due and two months before the deadline for filing dispositive motions. This late submission would prejudice plaintiff. Id. Defendant's motion for leave to file an amended answer and counterclaim will be denied with respect to its affirmative defense and counterclaim of inequitable conduct relating to the '579 patent.

ORDER

IT IS ORDERED that:

1. With respect to the disputed claim terms found in U.S. Patent No. 6,949,240, I construe the terms as follows:

- the “layer of tooth whitening composition” disclosed in claims 1 and 14 is separate from the “strip of material” disclosed in claims 1 and 14;
- the “strip of material” disclosed in claims 1 and 14 has a low flexural stiffness, but the “strip of material” disclosed in claims 1 and 14 is not indefinite and does not contain the following limitations: (1) it cannot dissolve or disintegrate in the mouth; (2) it is conformable to the countered surfaces of the teeth; (3) it serves as a substantially water impermeable barrier during use; (4) it is easily removable and intact after use and (5) it has structural integrity;
- “a gelling agent” as used in claims 9 and 19 means an agent that has the ability to form a gel; and
- “disposed on said strip of material” as used in claims 1 and 14 does not require construction.

2. With respect to the disputed claim terms found in U.S. Patent No. 6,551,579, I construe the terms as follows:

- “a layer of tooth whitening substance” disclosed in claims 1 and 11 is separate from the “strip of material” disclosed in claims 1 and 11;
- the “strip of material” disclosed in claims 1 and 11 has a low flexural stiffness

and is substantially water impermeable, but the “strip of material” disclosed in claims 1 and 11 is not indefinite and does not contain the following limitations: (1) it cannot dissolve or disintegrate in the mouth; (2) it is conformable to the countered surfaces of the teeth without permanent deformation; (3) it is easily removable and intact after use and (4) it has structural integrity;

- “a gelling agent” as used in claims 1, 3-6, 11 and 13-15 means an agent that has the ability to form a gel;
- the “release liner” disclosed in claims 1 and 11 does not contain the limitations that it be attached to the tooth whitening product and that it cannot be a package;
- “less affinity for said tooth whitening substance than said tooth whitening substance exhibits for itself and for said strip of material” as used in claims 1 and 11 could include zero affinity for the tooth whitening substance; and
- “thin” as used in claim 11 is not indefinite.

3. Defendant McNeil PPC, Inc.’s motion for leave to file its first amended answer and counterclaim is GRANTED with respect to its new factual allegations regarding inequitable conduct during the prosecution of the ‘240 patent and is DENIED with respect to its new affirmative defense and counterclaim of inequitable conduct regarding the ‘579 patent. Defendant may have until January 30, 2009, in which to file an amended answer and

counterclaim for the limited purpose of adding new factual allegations in accordance with this order.

Entered this 26th day of January, 2009.

BY THE COURT:

/s/

BARBARA B. CRABB

District Judge